5.0 SMDA Summary

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

1. **Name of Submiter**:

   Chris Zander
   Director of North American Operations
   1064 Labarge Rd
   Hudson, WI 54016-7340

2. **Device Name**:

Device Proprietary / Trade Name:	Sirocco™ Thermal Regulating System
Common Name:	Hyper/Hypothermia system
Classification Names:	System, Thermal regulatory
Device Classification:	Class II
Regulation Number:	21 CFR 870.5900
Product Codes:	DWJ

3. **Legally Marketed Equivalent Device Name**:

We are claiming substantial equivalence to:

- Augustine Medical, Inc. Bair Hugger Model 750 unit used with Bair Hugger blankets; K001149
- Augustine Medical, Inc. Bair Hugger Model 505 unit used with Bair Hugger blankets; K960167

4. **Description of the Device**:

The Sirocco™ temperature management system consists of a portable forced-air temperature management unit and a disposable forced-air blanket (various models).

5. **Intended Use of the Device**:

The Galmaz Biotech® SIROCCO™ Thermal Regulating System is intended to prevent and treat hypothermia and provide warmth to cold or shivering patients. In addition, the Galmaz Biotech® SIROCCO™ Thermal Regulating System should be used whenever conditions exist that could cause patients to become cold.

6. **Comparison of technological characteristics With Predicate Device**:

The Sirocco™ Thermal Regulating System is substantially equivalent in its technological characteristics as the predicate devices.

- Augustine Medical, Inc. Bair Hugger Model 750 unit used with Bair Hugger blankets; K001149
- Augustine Medical, Inc. Bair Hugger Model 505 unit used with Bair Hugger blankets; K960167

7. **Discussion of Non clinical Studies**:

Results of studies conducted on the sterile disposable Sirocco™ Thermal Regulating System forced-air blanket demonstrate the device is substantially equivalent in safety and effectiveness with the predicate devices.

In addition, the following standards and internal tests were conducted to ensure the safety of the user and patient.

STANDARDS	WARMING UNIT
IEC 60601-1:1993 + A1:1996 + A2:1996 + A2:1999 ERRATUM + A13:1997	Electronic Medical Equipment. Part 1: General requirements for safety
IEC 60601-1-2:2002 +A1:2006	Electronic Medical Equipment. Part 1-2: General requirements for the security. Collateral norm: Electromagnetic compatibility. Requirements and tests (IEC 60601-1-2: 2001/A1: 2004
IEC 60601-1-4:1997 +A1:2000	Electronic Medical Equipment. Part 1: General requirements for the security. 4: Collateral norm: Programmable Electronic Medical systems
UL 60601-1:2002	Medical Electrical Equipment, Part 1: General Requirements for Safety
IEC ISO 10993-1:2004	Biological sterile product evaluation. Part 1: Evaluation and tests.
IEC ISO 10993-7: 1996	Biological evaluation of sterile products. Part 7: Remainders in sterilization by ethylene oxide.

INTERNAL TESTS	**DESCRIPTION**
01	Initial Test of operation of electronic plates according to INS-B-001
02	Final assembly INS-B-001
03	Final verification of assembled product INS-B-002
	Visual Inspection
	Test of operation of alarms and security systems
	Pressure Test
	Temperature Test
	Electrical Safety Test
	Final Test
04	Final labeling of the equipment INS-B-003
05	Final packaging of the equipment INS-B-004

8. **Conclusion**:

The GALMAZ BIOTECH® Sirocco™ Thermal Regulating System has similar technological characteristics and the same intended use as devices currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 30 2011

Galmaz Biotech S.L.
c/o Mark Job
Regulatory Technology Services, LLC
1394 25th St. NW
Buffalo, MN 55313

Re: K102856
SIROCCO™ Patient Warming System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: June 15, 2011
Received: June 16, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Sirocco™ Thermal Regulating System.

Indications for Use:

The Galmaz Biotech® SIROCCO™ Thermal Regulating System is intended to prevent and treat hypothermia and provide warmth to cold or shivering patients. In addition, the Galmaz Biotech® SIROCCO™ Thermal Regulating System should be used whenever conditions exist that could cause patients to become cold.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102856